

## **REMARKS**

Favorable reconsideration and allowance of this application are requested.

### **1. Discussion of Amendments**

By way of the amendment instructions above, the minor typographical error helpfully noted by the Examiner has been corrected in claim 3.

Claims 13-16 directed toward a patentably distinct invention non-elected for prosecution herein have been canceled. Cancellation of such non-elected claims has however been effected without prejudice to the applicants' rights under 35 USC §121.

The specification on page 4, lines 23-33 has been amended so as to include the subject matter of original claim 6 (which constitutes its own disclosure). As such, no "new matter" has been presented by such specification amendment.

Therefore, following entry of this amendment, claims 1-12 will remain pending herein for which favorable action on the merits is solicited.

### **2. Response to 35 USC §112 Rejection**

Claim 6 attracted a rejection under 35 USC §112, first paragraph as allegedly failing to comply with the written description requirement of such statutory provision. Reconsideration and withdrawal of this rejection in view of the following comments are requested.

Applicants respectfully disagree with the Examiner's reasoning in paragraph 3 on page 2 of the Official Action. Technically, having linear densities of at most 10 deniers per filament makes perfect sense. Furthermore, such a claimed requirement is clearly

supported in the paragraph on page 4, lines 23-33<sup>1</sup>, particularly the following passage at page 4, lines 26-30:

“Furthermore, it was found that the quantity of abraded particles in the range from 0.5 to 10µm as a consequence of joint movements is relatively lower when the fibres consist of monofilaments with a titre of between 0.5 and 10 denier per filament (dpf) and preferably between 1 and 5 dpf.”

The later passage in the paragraph on page 4, lines 23-03 on which the Examiner apparently has focused to support the rejection under 35 USC §112 concerning *at least* 10 denier concerns the whole fiber -- that is the fiber formed by a number of (mono)filaments and not to the (mono)filaments per se.

Notwithstanding the above, the paragraph on page 4, lines 23-33 has been revised so as to include reference to the subject matter of original claim 6 (which constitutes its own disclosure).

In view of the above, therefore, applicants suggest that claim 6 is entirely commensurate with the written description requirement of 35 USC §112, first paragraph.

### **3. Response to 35 USC §103(a) Rejections**

The only issues remaining to be resolved in this application are the Examiner's rejections advanced under 35 USC §103(a). Specifically, claims 1-3 and 6-12 were rejected under 35 USC §103(a) as allegedly being unpatentable over Harpell et al '804 (USP 5,135,804) in view of Ward (USP 5,628,946), while claims 4 and 5 were rejected separately over Harpell et al '804 and Ward and further in view of Harpell et al '273

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<sup>1</sup> Page 4, lines 23-33 corresponds to paragraph [0016] in the published version of the subject application, i.e., US 2009-0143864, which was referenced by the Examiner in the Official Action.

(USP 4,455,273). Applicants respectfully suggest that none of the applied publications is appropriate as a reference against the presently claimed invention.

## **I. The Applied References**

Applicants note that Harpell et al '804 concerns fabrication of flat polyethylene film-like articles and not a shaped part suitable as a prosthetic joint. Particularly, Harpell et al '804 does not disclose a process of compressing between a hollow mould part and a plug as required by the pending claims herein.

The applied Ward patent concerns preparing a homogeneous polymeric monolith. Ward does not disclose manufacturing a prosthetic joint but merely mentions that the process may be used for manufacturing of orthodontic brackets, bone implants and body armor.

Harpell et al '273 concerns a process of manufacturing a polyethylene fiber or polypropylene fibre with a polymeric additive. A number of polyethylene polymers are mentioned having various intrinsic viscosities. However, the fibres of Harpell et al '273 would in many cases be unsuited for prosthetic joints, as the polymeric additives used in Harpell et al '273 would tend to lead to increased production of particles during use as compared to pure UHMWPE fibres.

## **II. Non-Obviousness of Claimed Invention**

Of those features defined by applicants' pending claim 1, Harpell et al '804 does not disclose or suggest at least the following:

- (i) a process for manufacturing a prosthetic joint with at least one loaded surface, and
- (ii) compressing between a hollow mould part and a plug.

Regarding feature (i), it must not be overlooked that such a claimed feature in fact serves to structurally distinguish the presently claimed invention as the reduction in production of particles is described as a key feature of the presently claimed invention. Such a claimed feature is not however important for all implants in general. See in this regard the discussion in MPEP 2111.02 II as exemplified by citations of *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333-34, 68 USPQ2d 1154, 1158 (Fed. Cir. 2003) and *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1346-48, 64 USPQ2d 1202, 1204-05 (Fed. Cir. 2002).

Applicants therefore respectfully submit that Harpell et al '804 does not disclose a process of making a part with a curved surface and particularly not in a one step process directly from a fabric. On the contrary, column 3, lines 30-32 of Harpell et al '804 disclose that if a shaped article is needed to be prepared from a woven article, then a film prepared from the fabric as described in Harpell et al '804 will need subsequent treatment after being transformed to the film and hence while it is no longer a fabric in the sense of Harpell et al '804 (see for example column 4, lines 5-15).

The examiner suggests that combining Ward with Harpell et al '804 cures the deficiencies of the latter. However, Ward does not disclose manufacturing a prosthetic joint but merely mentions that the process may be used for manufacturing of orthodontic brackets, bone implants and body armor. The insight that a prosthetic joint can be manufactured, from which during use involving sliding contact few particles are released with a size harmful for the human body, by compressing specifically a woven fabric of gel-spun UHMWPE fibres is completely lacking in Ward. Furthermore, as noted above the combination of the teachings of Harpell et al '804 and Ward would lead to a method, where first a film is prepared before allegedly forming a final product from this film. Such a method is much more complex than the present process and still misses any hint in the combined teachings that a prosthetic joint may be successfully prepared and even more that such a prosthetic joint would be successful during use as implant exposed to abrading wear due to reduction in production of particles.

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Claims 1-3 and 6-12 are patentably unobvious over Harpell et al '804 in view of Ward. Withdrawal of the rejection advanced against such claims under 35 USC §103(a) is therefore in order.

Harpell et al '273 when combined with Harpell et al '804 and Ward is likewise insufficient to render obvious claims 4 and 5. Specifically, even though the fibers of Harpell et al '273 may be employed in the process of Harpell et al '804, the inadequacies of such process as discussed above would still be present. Therefore, claims 4 and 5 are likewise patentably unobvious over Harpell et al '804 and Ward when further combined with Harpell et al '273.

In view of the above, applicants suggest that all pending claims herein are allowable over the applied references of record. Early receipt of the Official Allowance Notice is therefore awaited.

#### **4. Fee Authorization**

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140.

Respectfully submitted,

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